K034057

MAR - 9 2004

SECTION 7

Premarket notification summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 21 CFR 807.92

The assigned 510(k) number is:

Date of summary preparation:	July 15 2002
Submitter's name:	Mr. Joël Lesser
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Contact :	Mr. Joël Lesser
Device name:	***Lacrytest***
Trade name:	***Lacrytest***
Classification name:	***Immunological test***

- **7- PREMARKET NOTIFICATION 510(K) SUMMARY.**

7-1 Predicate device.

Device Classification Name	IGE, ANTIGEN, ANTISERUM, CONTROL
Regulation Number	866.5510
510(K) Number	K964152
Device Name	UNICAP TOTAL IGE ASSAY/PHARMACIA TOTAL IGE CONTROL

ADIATEC SA Company asserts that the UniCAP total IgE FEIA Assay is substantially equivalent to the Lacrytest. Each product is designed to measure the level of total IgE. Each product is an Immuno Assay.

7-2 Intended use.

Lacrytest is a rapid immunoassay for the total IgE detection in tears. Normal values are below 2,5 kUI/l, (3 ng/ml). This assay indicates in a qualitative way the presence of total class E immunoglobulins in tears, with level above normal value.
Lacrytest offers help for ocular allergy diagnosis in a simple and fast way.
Lacrytest is to be used with IgE mediated allergic ocular disorders.
It allows knowing if an ocular inflammation, conjunctivitis, or dry eyes symptom could be linked to allergic ocular disorder.
This test is dedicated to the physicians and clinical Laboratory.

7-3 General description

LACRYTEST (marked CE) allows the rapid and specific determination of total IgE in tears (in vivo/in vitro).
This test is a simple and rapid immuno-chromatographic test, which enables the identification of allergic conjunctivitis in one single step. Its main advantage is that it can be done in vivo without being invasive. The speed and simplicity of this unique test enables a better and faster treatment of the patient.

7-4 Description of the device.

Lacrytest, a simple and rapid immuno-chromatographic test, enables the identification of allergic conjunctivitis in one single step. The speed and simplicity of this unique test enables better and faster care and treatment of the patient.

Lacrytest is a ready–to-use strip, with all the necessary reagents already incorporated into it. No instrumentation or prior provision of tear samples is required: Lacrytest uses monoclonal and polyclonal antibodies to detect total IgE in tears. Lacrytest gives results from just one teardrop, and is placed in contact with the patient's eye for less than three minutes., causing minimum discomfort when compared to the Schirmer assay. Doctors do not have to take tear sample, and an indicator appears on the strip when enough tear fluid has been absorbed. The test strip is then soaked with sterile water and the evaluation of amount of total IgE detected.

The results appear in the form of easily visible red-violet lines in the presence of total IgE levels greater than 2,5 KUI/L (the detection limit). These results are stable and can be archived. The test can be used in the laboratory, in the doctor's surgery or on a home visit.

7-5 Qualitative constitution of the reagent:

Chemical products:

- trihydrated tetrachloroauric acid (III): HAu Cl4 3H20
- Natrium Azide: NaN3
- Polyethylen glycol 20000: HO (C2H4O)n H
- Hydrolyzed Polyvinyl Alcohol, 80%
- Sucrose 98%: D(+) saccharose
- Thimérosal to 0,001%

Materials:

- Nitrocellulose
- Polyester resin fibers,
- Cellulose,
- Adhesive band
- The band in contact with the eye is a membrane constituted of polyester fibers and a surfactant. Those two components, "Pall Profile Filter" and "Bioinert Filter", are unprovided with toxicity as specified in the toxicity tests certificates enclosed in the annex.

Biological products:

- Monoclonal Antibodies and mouse and goat polyclonal antibodies, purified with affinity chromatography, specific of type E human immunoglobulins (hIgE) and type G.mouse immunoglobulins
- Cream milk Gloria Nestlé
- Purified Bovine Serum Albumin: animal origin

7- 6 Performance equivalence: Technology comparison.

UniCAP uses the ELISA method whereas ADIATEC develops immuno-chromatographic assay. UniCAP can give total IgE levels accurate measurement and uses 48 different parameters.

Lacrytest is a ready-to-use strip, with all the necessary reagents already incorporated into it. No instrumentation or prior provision of tear is necessary. The total IgE level is given on the strip.

Contrary to that, UniCAP needs blood sampling and so human serum, or a high volume of tears. The results are given with UniCAP 100 Instrument which is programmed to automatically calculate data from UniCAP total IgE assay. The total IgE values for controls and patient samples are automatically calculated and printed out

- Like the LACRYTEST, UniCAP total IgE Assay is an in vitro Assay for the measurement of total IgE. An other common point is the fact that the both devices are to be used in clinical laboratories.

But contrary to UniCAP, Lacrytest is furthermore to be used in medical offices.

7-7 Performance Equivalence-method comparison.

- Comparative studies, carried out on 165 human serums with reference to the UniCAP, have shown that it has a sensitivity of 91.7% and a specificity of 98.5%.

- We can make a parallel between the precision of the Lacrytest and the precision of the UniCAP:

Precision: Lacrytest

Intra-run	L0	L1	L2	L3
Number of determinations	30	30	30	30
Total IgE levels KUI/L	0	5	20	50
Ranges (intensities)	0	0 - 1	2 - 3	3 – 3
Mean value (intensity)	0	1	2	3
Variance %	0	7	3	0

Inter-run	L0	L1	L2	L3
Number of determinations	20	20	20	20
Total IgE levels KUI/L	0	5	20	50
Ranges (intensities)	0	0 – 1	2 - 3	3 – 3
Mean value (intensity)	0	1	2	3
Variance %	0	10	4	0

Precision: UniCAP

Serum level KIU/l	Coefficients of variation (%) Within assay	Between
13	2.8	8.9
75	2.0	5.3
640	2.8	9.1

The coefficient of variation of UniCAP is similar at low levels (13 kIU/l) than high levels. Lacrytest has a higher coefficient of variation for low levels (5 kIU/l), but its coefficient of variation is similar for level of 20 kIU/l.

- We can make a parallel between the sensitivity and specificity of the Lacrytest and those of the UniCAP:

Lacrytest has a detection limit of 2,5 kIU/l and the UniCAP detection limit is < 2 kIU/L.

UniCAP mean recovery is 98+/-5%

The sensitivity of Lacrytest is 91.75% and its specificity 98.53%
Then, Lacrytest has a slightly lower sensitivity than UniCAP and an equal specificity.

7-8 Quality of semi-quantitative Lacrytest results:

Agreement of negative results is 87,79% and agreement of positive results is 84,21%, mainly explained by the human reading of the device.

Accuracy determination of semi-quantitative results is of 100% except near the upper limit of the Intensity 2 (30 kIU/l) where upper estimation can occur.

7-9 Comparing results obtained by professional Lab technicians with persons at the point of care facilities:

No significant differences occurred between the different sites regarding the negative samples.
Some differences have been observed concerned the agreement of IgE concentration categories, mainly concerning an upper estimation of the IgE levels

7-10 Percentage of normal healthy subjects with a Lacrytest response less than 2.5kIU/liter

87% of normal healthy subjects give a Lacrytest response negative, i.e. less than 2,5 kIU/l. 13% of normal healthy subjects give an Intensity 1 Lacrytest results (low positive).
Further studies are in course to determine the prognostic value of this Lacrytest range intensity regarding the presence of an allergic field.

7-11 6-9-13 Manufacturing information :

Manufacturing quality control are performed on final packaging strips using the NIBSC Standard 75/502.

Samples of each batch are kept in room temperature storage for a follow up of the batches.

CONCLUSION

The data presented in the summary of safety and effectiveness is the data that the food and drug administration used in granting DPC substantial equivalence for the LACRYTEST.

Mr Joël LESSER
President of ADIATEC SA

DÉCEMBER 19/2003
Dated

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Joel Lesser
President
Adiatec SA
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France 44000

MAR - 9 2004

Re: k034057
Trade/Device Name: Lacrytest
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E immunological test system
Regulatory Class: Class II
Product Code: DGC
Dated: December 20, 2003
Received: December 30, 2003

Dear Mr. Lesser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K034057

Device Name: **LACRYTEST**

Indications For Use:

Lacrytest is a rapid immunoassay for the detection of total IgE in tears. Semi-quantitative detection of total IgE in tears (< 2.5 kIU/liter, 2.5 - 10 kIU/liter, 10 - 40 kIU/liter, and > 40 kIU/liter) indicates local IgE production associated with allergic conjunctivitis. This test is used in the physician office and professional clinical laboratories.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria Chan
Division Sign-Off

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Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K034057